K951620

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION
FOR
MIDMARK™ MIDLINE CATHETER

APR - 4 1996

1. Classification Name: Catheter, Intravascular 80FOZ
   Common Name: Peripherally Inserted Catheter
   Proprietary Name: MIDMARK™ Midline Catheter

2. Establishment Registration Number: 2938241

3. Establishment Name/Address: Menlo Care, Inc.
   1350 Willow Rd., Suite 101
   Menlo Park, CA 94025

4. Classification: Class II

5. Substantially Equivalent Devices: V-Cath® ML, L-CATH® Mid Line (K924968)

6. Description and Device Function: Peripherally inserted catheter for venous access or intravenous therapy. Method of insertion is through an introducer. The optimal catheter tip location is below the shoulder at the level of the axilla. The products will be available in single and dual lumen configurations; as sterile individual units or in trays along with the components used for insertion.

7. Component Specifications: All Midmark components and materials are identical to that of Centermark (K920828).

8. Performance Standards: No performance standards have been established by the FDA.

9. Packaging and Sterilization: These devices will be packaged in peelable polymer pouches and sterilized by exposure to high energy electron radiation. Insertion trays will be sterilized by exposure to ethylene oxide.

   Non-pyrogenicity will be established for each production lot by the LAL procedure.